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| 10/597,851 | 08/09/2006 | Karlheinz Bortlik | 112701-746 | 7063 |

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| EXAMINER |
|---|
| CHEN, CATHERYNE |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1655 | |

| NOTIFICATION DATE | DELIVERY MODE |
|---|---|
| 01/30/2008 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATENTS@BELLBOYD.COM

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/597,851 | BORTLIK ET AL. | |
| | Examiner | Art Unit | |
| | Catheryne Chen | 1655 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *01 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-4,6-9 and 11-26* is/are pending in the application.

4a) Of the above claim(s) *17-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 6-9, 11-16, 22-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

The Amendments filed on Nov. 1, 2007 has been received and entered. Currently, Claims 1-4, 6-9, 11-26 are pending. Claims 1-4, 6-9, 11-16, 22-26 are examined on the merits. Claims 5 and 10 are canceled.

### *Election/Restrictions*

Applicant's election without traverse of Group I (Claims 1-16, 22-24) in the reply filed on May 9, 2007 is acknowledged.

Claims 17-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on May 9, 2007.

### *Claim Rejections - 35 USC § 112*

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 16, 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 16 and 25 recite the limitation "the content." There is insufficient antecedent basis for this limitation in the claim. Amendments in Claims 9 and 15 refer to "a primary composition" but not referring the composition as "the content." Thus, there is lack of antecedent.

### *Response to Arguments*

### *Claim Rejections - 35 USC § 102*

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4, 6, 8, 9, 11-15, 22, 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Hartal et al. (US 5965183) for the reasons set forth in the previous Office Action. All of Applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that the reference fails to disclose each and every element of the claims.

Hartal et al. teaches lycopene concentrates for use in food coloring, nutraceuticals, pharmaceuticals, and cosmetic formulations, lyopenes from vegetable extracts (column 1, lines 7-9, 16-19), food-compatible liquid, pharmaceutically-acceptable liquid, cosmetically-acceptable liquid (column 6, lines 26-42), oleoresin contains about 2-10% lycopene (Claim 17). Thus at least one carotenoid compound is taught by the reference.

Hartal et al. does not specifically teach using lycopene to treat skin. However, the method of treating skin is considered to inherently teach the claimed method because both the reference and the claimed invention are administering the same composition to the same patient. The patient is the same because every person has skin. Thus, on the administration of lycopene to any patient, a treatment of skin would have had to occur if applicant's invention function as claimed.

Claims 1-4, 6, 8, 9, 11-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Rodriguez et al. (US 6329557 B1) for the reasons set forth in the

previous Office Action. All of Applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that the reference fails to disclose each and every element of the claims and there is no enrichment of cis-carotenoid.

Rodriguez et al. teaches carotenoids from plants, fish, crustaceans, birds, algae, and bacteria, to isolate beta-carotene, lutein and zeaxanthin, capsanthin, canthaxanthin, and astaxanthin (column 1, lines 9-20), where the concentration of carotenoids in the dispersion is between about 0.1 to 15 grams per kilogram of the extract (Claim 17), for use in pigmenting formulations as animal feed (column 1, lines 26-27). Cis forms of carotenoids occur naturally; therefore, isolation of carotenoids lead to enrichment of cis forms of carotenoids. Thus, at least one carotenoid is taught and extract of the carotenoid leads to enrichment of the carotenoid.

Claims 1-4, 6, 8, 9, 11-16, 22, 24-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Haigh (US 5310554) for the reasons set forth in the previous Office Action. All of Applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that the reference fails to disclose each and every element of the claims and there is no enrichment of cis-carotenoid.

Haigh teaches composition of purified natural beta-carotenes and methods for purification from plants. The beta-carotene preparations are enriched in the 9-cis isomer. Purified beta-carotenes are useful as dietary

vitamin A supplementation, as pharmaceuticals, as anti-oxidants in therapeutic and preventative applications (column 1, lines 5-14). Carotenes can be extracted from vegetables, fruits, algae. Beta-carotene can prevent or reduce the risk of heart disease and stroke and cancers, such as breast, lung, colon, prostate, and cervix (column 1, lines 28-29, 33-36). The composition may comprise carotenoids, cis-beta carotene isomers about 3% or less. The high purity natural beta-carotene preparations may be combined with pharmaceutically acceptable carriers, preservatives, vitamin supplements or other medicinal agents in a variety of formulations and dosages for administration to humans or other animals. The formulation are typically a capsule, liquid, tablet or powder (column 2,lines 31-51). For solid compositions, the compounds can be with conventional carriers, glucose, sucrose, and may contain about 10-100% active ingredients (column 6, lines 24-36). As a dietary supplement, 9-cis beta-carotene may be supplied as an oil, suspended in a capsule, beadlet, or incorporated directly into foodstuffs (column 6, lines 48-52). The pharmaceutical compositions are for oral, local, topical or parenteral administration for prophylactic or therapeutic treatment (column 8, lines 54-59). Cis forms of carotenoids occur naturally; therefore, isolation of carotenoids lead to enrichment of cis forms of carotenoids. Thus, at least one carotenoid is taught and extract of the carotenoid leads to enrichment of the carotenoid.

Haigh does not specifically teach using carotenoids to treat skin. However, the method of treating skin is considered to inherently teach the claimed method because both the reference and the claimed invention are

administering the same composition to the same patient. The patient is the same because every person has skin. Thus, on the administration of carotenoids to any patient, a treatment of skin would have had to occur if applicant's invention function as claimed.

## *Claim Rejections - 35 USC § 103*

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4, 6-9, 11-16, 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haigh (US 5310554) for the reasons set forth in the previous Office Action. All of Applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that there is no suggestion to combine the references and each element is not taught.

Haigh teaches composition of purified natural beta-carotenes and methods for purification from plants. The beta-carotene preparations are enriched in the 9-cis isomer. Purified beta-carotenes are useful as dietary vitamin A supplementation, as pharmaceuticals, as anti-oxidants in therapeutic and preventative applications (column 1, lines 5-14). Carotenes can be extracted from vegetables, fruits, algae. Beta-carotene can prevent or reduce the risk of heart disease and stroke and cancers, such as breast, lung, colon, prostate, and cervix (column 1, lines 28-29, 33-36). The composition may comprise carotenoids, cis-beta carotene isomers about 3% or less. The high purity natural

beta-carotene preparations may be combined with pharmaceutically acceptable carriers, preservatives, vitamin supplements or other medicinal agents in a variety of formulations and dosages for administration to humans or other animals. The formulation are typically a capsule, liquid, tablet or powder (column 2,lines 31-51). For solid compositions, the compounds can be with conventional carriers, glucose, sucrose, and may contain about 10-100% active ingredients (column 6, lines 24-36). As a dietary supplement, 9-cis beta-carotene may be supplied as an oil, suspended in a capsule, beadlet, or incorporated directly into foodstuffs (column 6, lines 48-52). The pharmaceutical compositions are for oral, local, topical or parenteral administration for prophylactic or therapeutic treatment (column 8, lines 54-59). Cis forms of carotenoids occur naturally; therefore, isolation of carotenoids lead to enrichment of cis forms of carotenoids. Thus, at least one carotenoid is taught and extract of the carotenoid leads to enrichment of the carotenoid.

Haign teaches that oleoresin composition can be used topically. Thus, an artisan of ordinary skill would reasonably expect that oleoresin composition could be used as the types of method to prevent or treat “sensible, dry or reactive” skins. This reasonable expectation of success would motivate the artisan to use oleoresin composition in a liquid composition to treat skin in the reference composition. Thus, using oleoresin composition is considered an obvious modification of the reference.

The reference does teach that each of the claimed ingredients is suitable for combination in a pharmaceutical composition. Thus, an artisan of ordinary skill would be reasonably expected that the claimed ingredient could be combined together to produce a single pharmaceutical product. This reasonable expectation of success would motivate the artisan to combine the claimed ingredients together into a single composition.

## *Conclusion*

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

## *Contact Information*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catheryne Chen whose telephone number is

571-272-9947. The examiner can normally be reached on Monday to Friday, 9-5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Susan Hoffman/
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January 15, 2008